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PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE TECH CENTER 1600/2900

Applicant : Denise Faustman Art Unit : 1648
Serial No. : 08/925,627 Examiner : L. Scheiner
Filed : September 9, 1997 Customer No.: 21559
Title : METHODS FOR INHIBITING REJECTION OF TRANSPLANTED
TISSUE

Assistant Commissioner of Patents
Washington, DC 20231

REPLY TO EXAMINER'S ACTION

In reply to the Examiner's Action mailed September 12, 2000, kindly consider the following remarks.

REMARKS

Applicant's claims have been found by the Examiner to be directed to allowable subject matter. The sole issue remaining in this case focuses on whether applicant's specification enables masking agents other than F(ab')₂. The enablement rejection is grounded in the notion that the specification teaches several F(ab')₂ fragments, but nowhere teaches additional masking agents such as intact antibodies, receptors, or ligands

for preparing the claimed transplantable compositions. Applicant respectfully disagrees.

Applicant's specification clearly teaches a broad range of non-lytic masking agents, and such agents are in no way limited to F(ab')₂ fragments. On this point, the Examiner's attention is directed to applicant's specification, where numerous suitable masking agents are specified. At pages 8-9, for example, under the heading "Non-Lytic Masking Agents," applicant describes at least three categories of such masking agents. These include (1) antibodies or fragments or derivatives thereof; (2) soluble fragments or analogs of antigen-specific host T-cell receptors; and (3) synthetic molecules that mimic T-cell receptors. These non-lytic masking agents are accordingly also included in the invention. Thus, contrary to the assertion found in the office action (p. 2, lines 15-16), applicant's specification describes how to make transplantable compositions having surface antigens masked with whole antibodies or antibody fragments, or even receptors or ligands.

Furthermore, no evidence currently made of record in this case establishes a basis for doubting the objective truth of the statements found in applicant's specification regarding the enablement of the present invention. In addition, as is discussed above, applicant's teach the existence of several non-lytic masking agents other than F(ab')₂. Under these facts, cases such as *In re Marzocchi*, 439 F.2d 220, 169 U.S.P.Q. 367 (C.C.P.A. 1971), compel withdrawal of the section 112, first paragraph rejection.

Finally, on the issue of claim breadth, applicant notes that limiting the claims

along the line suggested by the Examiner would unacceptably narrow the coverage to transplantable compositions masked with a F(ab')₂. A potential infringer would easily avoid infringement by simply reading applicant's specification and using any of the alternatives taught there. Such claims would not adequately protect the inventor. See *In re Goffe* 542 F.2d 564, 567, 191 U.S.P.Q.2d 429, 431 (C.C.P.A. 1976) (“[T]o provide effective incentives, claims must protect adequately inventors. To demand that the first to disclose shall limit [his or her] claims to what [he or she] has found will work ... would not serve the constitutional purpose of promoting progress in the useful arts.”)

In sum, applicant's specification enables numerous non-lytic masking agents encompassed by the present claims, and applicant respectfully requests that this basis for the rejection under § 112 should be withdrawn.



CONCLUSION

In view of the foregoing remarks, Applicant submits that the claims are now in condition for allowance, and such action is respectfully requested. If the Examiner believes that a phone conference would be beneficial to the quick allowance of this case, she is requested to call Applicant's attorney at the number listed below.

Applicant also respectfully requests that the Preliminary Amendment mailed to the Patent Office on February 16, 1999 be entered into the record. A copy of this Amendment is enclosed.

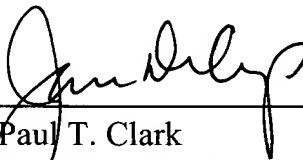
If there are any charges or credits, please apply them to deposit account number 03-2095.

Respectfully submitted,

Date: 12 February 2001

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00786.036005 Reply to Examiner's Action mailed 09.12.00.wpd



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